

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/AU2004/001487

## A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. <sup>7</sup>: A61M 1/12

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DWPI IPC A61M 1/10/- A61M 1/12/- + keywords (VAD, aorta, artery, cardi, ventric, assist, pump, actuator, balloon, bladder, shroud, wrap, limit, restrain and similar terms)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages               | Relevant to claim No.                      |
|-----------|--|--|
| X<br>Y    | WO 2002/024255 A1 (SUNSHINE HEART COMPANY PTY LTD) 28 March 2002<br>Pages 10-15, figures.        | 1-4, 6, 56, 57<br>15-25, 27, 29,<br>34, 38 |
| X<br>Y    | US 4051840 A (KANTROWITZ et al ) 4 October 1977<br>Whole document                                | 1-9<br>15, 17, 18, 29,<br>38               |
| X         | WO 2000/076288 A2 (SUNSHINE HEART COMPANY PTY LTD) 21 December 2000<br>Pages 11-16, figures 8-10 | 1-6, 56, 57                                |
| X         | US 4881939 A (NEWMAN) 21 November 1989<br>Columns 3-5, figures 8a-8b and 13a-13c                 | 1-4, 6                                     |



Further documents are listed in the continuation of Box C



See patent family annex

|   |  |
|---|--|
| <p>* Special categories of cited documents:</p>   |  |
| "A" document defining the general state of the art which is not considered to be of particular relevance  | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  |
| "E" earlier application or patent but published on or after the international filing date   | "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone   |
| "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "O" document referring to an oral disclosure, use, exhibition or other means  | "&" document member of the same patent family  |
| "P" document published prior to the international filing date but later than the priority date claimed  |  |

Date of the actual completion of the international search  
1 December 2004

Date of mailing of the international search report

27 JAN 2005

Name and mailing address of the ISA/AU

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## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No.      |
|-----------|--|----------------------------|
| Y         | WO 2001/013974 A2 (L.VAD TECHNOLOGY INC) 1 March 2001<br>Pages 8-14 and figures.   | 3-7, 11-25, 27, 29, 38     |
| X         | US 4630597 A (KANTROWITZ et al) 23 December 1986<br>Whole document   | 42, 43, 50, 52-55          |
| Y         |  | 4-7, 11-25, 27, 29, 34, 38 |
| X         | FR 2645739 A1 (VM TECH SA) 19 October 1990<br>Whole document   | 1-5, 8                     |
| Y         |  | 11-14                      |
| X         | WO 2002/024254 A2 (IMPERIAL COLLEGE INNOVATIONS LTD) 28 March 2002<br>Pages 14, 15 and figures   | 1-4, 6, 56, 57             |
|           | US 4630597 (column 3) provides the feature of bushing to be read with Y documents WO 2002/024255, US 4051840, WO 2001/013974, FR 2645739 and US 4630597. |                            |
|           | WO 2001/013974 is to be read with WO 2002/024255 for claims 19, 20, 27, 38.  |                            |

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**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
3. ☒ Claims Nos.: **58, 59**  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:  
See extra sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

**Supplemental Box**

(To be used when the space in any of Boxes I to VIII is not sufficient)

**Continuation of Box No: III**

**The International Searching Authority found multiple inventions in the present application as follows:**

Group 1: Claims 1-10, 56, 57 define an actuator for a heart assist device having first and second body portions in which the first special technical features is a shroud or wrap

Group 2: Claims 11-14 define an actuator for a heart assist device having balloon first and second body portions in which the second special technical feature is a bushing

Group 3: Claims 15-41 define a heart assist device having balloon first and second body portions and both the first and second special technical features, and could be considered with either group 1 or group 2. It is noted, however, that group 1 does not include the second special feature and group 2 does not include the first special feature.

Group 4: Claims 42-55 define a flexible inflatable balloon for a blood displacing heart assist device having first and second body portions in which the third special technical feature is a connecting body portion which is adapted to maintain a radius of curvature during movement of the second body portion between deflation and inflation of the balloon.

Group 5: The scope of claim 58 is unclear because of its multiple dependencies.

Group 6: The scope of claim 59 is unclear because of its multiple dependencies.

The features held in common by the claims are a balloon having first and second body portions which does not provide novelty or inventive step for the application because these features are provided by US 4881939, WO 2002/024255 and WO 2001/013974 as examples only amongst other citations.

No other feature which could provide novelty or inventive step for the application as a whole is found common to all the groups of claims.

Consequently the application lacks unity of invention.

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent Document Cited in<br>Search Report |             |     |          | Patent Family Member |            |    |            |
|---|-------------|-----|----------|----------------------|------------|----|------------|
| WO  | 2002/024255 | AU  | 91488/01 | EP                   | 1318848    | US | 2004073080 |
| US  | 4051840     | NIL |          |                      |            |    |            |
| WO  | 2000/076288 | AU  | 50548/00 | BR                   | 0011464    | CA | 2375962    |
|   |             | EP  | 1185319  | US                   | 2004167376 |    |            |
| US  | 4881939     | NIL |          |                      |            |    |            |
| US  | 4630597     | NIL |          |                      |            |    |            |
| WO  | 2001/013974 | AU  | 69241/00 | CA                   | 2382671    | EP | 1207921    |
| FR  | 2645739     | NIL |          |                      |            |    |            |
| WO  | 2002/024254 | AU  | 90088/01 | BR                   | 0114087    | CA | 2421812    |
|   |             | EP  | 1379294  | US                   | 2003233023 |    |            |

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX

# PATENT COOPERATION TREATY

From the:  
INTERNATIONAL SEARCHING AUTHORITY

REC'D 08 FEB 2005

WIPO

PCT

**PCT**

To:

SPRUSON & FERGUSON  
GPO Box 3898  
SYDNEY NSW 2001

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing  
(day/month/year) 27 JAN 2005

Applicant's or agent's file reference  
635200C

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
**PCT/AU2004/001487**

International filing date (day/month/year)  
28 October 2004

Priority date (day/month/year)  
11 November 2003

International Patent Classification (IPC) or both national classification and IPC  
**Int. Cl. <sup>7</sup> A61M 1/12**

Applicant

**SUNSHINE HEART COMPANY PTY LTD et al**

### 1. This opinion contains indications relating to the following items:

- |                                     |              |  |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the opinion   |
| <input type="checkbox"/>            | Box No. II   | Priority   |
| <input checked="" type="checkbox"/> | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability   |
| <input checked="" type="checkbox"/> | Box No. IV   | Lack of unity of invention   |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited  |
| <input checked="" type="checkbox"/> | Box No. VII  | Certain defects in the international application   |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application  |

### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

### 3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the IPEA/AU  
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PO BOX 200, WODEN ACT 2606, AUSTRALIA  
E-mail address: pct@ipaustalia.gov.au  
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Authorized Officer  
**SUE THOMAS**  
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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

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**PCT/AU2004/001487**

| <b>Box No. I</b> | <b>Basis of the opinion</b> |
|------------------|-----------------------------|
|------------------|-----------------------------|

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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**Box No. III**      **Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application  
☒ claims Nos: **58, 59**

because:

- ☐ the said international application, or the said claim Nos.  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos.  
are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos.  
are so inadequately supported by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. **58, 59**

- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form      ☐ has not been furnished

☐ does not comply with the standard

the computer readable form      ☐ has not been furnished

☐ does not comply with the standard

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

- ☐ See Supplemental Box for further details.



**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

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**Box No. IV      Lack of unity of invention**

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
- ☒ paid additional fees
- ☐ paid additional fees under protest
- ☐ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
- ☒ not complied with for the following reasons:

Claims 1-10, 56, 57 define an actuator for a heart assist device having first and second body portions in which the first special technical feature is a shroud or wrap

Claims 11-14 define an actuator for a heart assist device having balloon first and second body portions in which the second special technical feature is a bushing

Claims 15-41 define a heart assist device having balloon first and second body portions and both the first and second special technical features

This group could be considered with either of the preceding groups, but its essential features would only be covered if both groups were searched

Claims 42-55 define a flexible inflatable balloon for a blood displacing heart assist device having first and second body portions in which the third special technical feature is a connecting body portion which is adapted to maintain a radius of curvature during movement of the second body portion between deflation and inflation of the balloon

Claim 58 The scope of claim 58 is unclear because of its multiple dependencies

Claim 59 The scope of claim 59 is unclear because of its multiple dependencies

The features held in common by the claims are a balloon having first and second body portions which does not provide novelty or inventive step for the application because these features are provided by US 4881939, WO 2002/024255 and WO 2001/013974 as examples only amongst other citations.

No other feature which could provide novelty or inventive step for the application as a whole is found common to all the groups of claims.

Consequently the application lacks unity of invention.

4. Consequently, this opinion has been established in respect of the following parts of the international application:
- ☐ all parts
- ☒ the parts relating to claims Nos. **1-57**

**WRITTEN OPINION OF THE  
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International application No.

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**Box No. V**      **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

|                               |   |     |
|-------------------------------|---|-----|
| Novelty (N)                   | Claims 10-41, 44-49, 51                               | YES |
|                               | Claims 1-9, 42, 43, 50, 52-57                         | NO  |
| Inventive step (IS)           | Claims 10, 26, 28, 30-33, 35-37, 39-41, 44-49, 51     | YES |
|                               | Claims 1-9, 11-25, 27, 29, 34, 38, 42, 43, 50, 52-57, | NO  |
| Industrial applicability (IA) | Claims 1-57   | YES |
|                               | Claims  | NO  |

2. CITATIONS AND EXPLANATIONS:

|    |                |    |                |
|----|----------------|----|----------------|
| D1 | WO 2002/024255 | D2 | US 4051840     |
| D3 | WO 2000/076288 | D4 | US 4881939     |
| D5 | WO 2001/013974 | D6 | US 4630597     |
| D7 | FR 2645739     | D8 | WO 2002/024254 |

NOVELTY (N) Claims 1-9, 42, 43, 50, 52-57

Claims 1-4, 6: The features of each of these claims are provided by each of D1, D2, D3, D4, D7 and D8. For example only, in D1, see the following features:

|   |          |
|---|----------|
| Inflatable balloon having first and second body portions joined by flexure region   | Figure 3 |
| Shroud or wrap adjacent first body portion  | Item 28  |
| Peripheral extent of shroud/wrap at least equal to extent of balloon flexure  | Figure 3 |
| Shroud/wrap restrains part of first body portion at/near flexure region against displacement towards shroud/wrap past a predetermined limit | Figure 3 |
| Shroud/wrap allows unrestrained displacement away from shroud or wrap   | Figure 3 |

Similarly, D2, D3, D4, D7 and D8 provide the features of claim 1.

The features of claims 2-4 and 6 are provided by D2, D3, D4, D7, D8 in the same manner as the above.

Claim 5: All the features of claim 5 are provided by each of D2, D3 and D7 in the same manner as above.

Claims 7-9: All the features of each of these claims are provided by D2 similarly to the above, claim 8 also by D7.

Claims 42, 43, 50, 52-55: All the features of each of these claims are provided by D6 similarly to the above.

Claims 56 and 57: All the features of each of these claims are provided by each of D1, D3 and D8 similarly to above.

INVENTIVE STEP (IS) Claims 1-9, 42, 43, 50, 52-57

Claims 1-9, 42, 43, 50, 52-57: Since these claims lack novelty, they also lack inventive step.

Claims 4-7: Each of the features added by each of claims 4-7, shroud inwardly concave, elongated and elliptical, body portions and flexure integrally formed, formed by dip moulding, are also provided by each of D5 and D6.

Claims 11-14: When D6 and D7 are read together as would be considered obvious by a person skilled in the art, all the features of each of these claims is disclosed.

Claims 15-18, 21-25, 29, 34, 38: When D1 is read with D6, similarly, all the features of each of these claims is disclosed.

Claims 19, 20, 27: When D1 is read with D5, similarly, all the features of each of these claims is disclosed.

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**Box No. VIII    Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The scopes of claim 58 and claim 59 are unclear because of their multiple dependencies.